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Intracoronary Ultrasound Observations During Stent Implantation

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The Palmaz-Schatz stent has been used successfully to improve primary angioplasty results, to treat large coronary dissections, or to prevent impending closure of the lumen.¹⁻¹⁵ The determination of successful stent implantation is based on the angiographic appearance. However, angiographic projection imaging may not reveal the three-dimensional geometry that is necessary to appreciate full expansion of a cylindrical meshwork device such as the intracoronary stent. Intravascular ultrasound (IVUS) imaging has the advantage of providing detailed cross-sectional images from within the vessel lumen, allowing better evaluation of stent expansion.¹⁶⁻²¹ Based on angiographic assessment, it has been recommended to overdilate the stenosis about 10% greater than the reference vessel diameter.¹ There is no quantitative guideline for IVUS assessment of successful stent implantation. The purpose of this study was to compare the observations of IVUS with standard angiography after stent implantation and to develop recommendations for guiding stent implantation by IVUS.

Methods

Population and Stent Type

The study population consisted of 63 consecutive patients who underwent Palmaz-Schatz stent insertion for native coronary arteries and received IVUS imaging at two institutions from January 1, 1993, to April 16, 1993. There were 55 men and 8 women. The mean patient age was 58.6 ± 9.6 years. All patients had coronary artery stenosis with objective evidence of ischemia. Of the 65 lesions treated, the indications for stent insertion were elective implantation in 60 (92%) and emergency implantation in 5 (8%). Emergency stent deployment was defined as the presence of a large dissection with threatened closure after coronary angioplasty, as evidenced by chest pain and ischemic ECG changes. The target lesion was in the left anterior descending coronary artery (LAD) in 40 lesions, the left circumflex artery (LCx) in 10 lesions, the right coronary artery (RCA) in 14 lesions, and the left main artery in 1 lesion. A standard-length (15 mm) Palmaz-Schatz stent (Johnson and Johnson Interventional Systems) was used in 12 lesions (18%). A short version (7 mm) of the Palmaz-Schatz stent was made by cutting the articulation site²² and was used in 48 lesions (74%). A 10-mm-long biliary Palmaz stent was

inserted in 10 lesions (15%). One stenosis was treated with a 10-mm renal Palmaz stent. The biliary and renal stents were used in heavily calcified lesions because of the additional strength of these larger devices. A single stent was implanted in 18 lesions (28%), and multiple stents were used in 47 lesions (72%).

Anticoagulation

All patients received aspirin 325 mg and a calcium channel antagonist before stent implantation. Heparin (10 000 U) was administered intra-arterially at the beginning of the procedure and was followed by intravenous infusion to maintain the activated clotting time ≥ 300 seconds. Low-molecular-weight dextran 40 (10%) was administered (100 mL/hr for 2 hours) and continued at 50 mL/hr for a total dose of 1 L. The sheaths were pulled 1 day after the procedure. Patients were maintained on a heparin infusion for 4 to 5 days until a therapeutic warfarin dose was achieved with a prothrombin time between 16 and 18 seconds. Patients stayed in the hospital for 7 days after the procedure. Dipyridamole and sodium warfarin were continued for 2 months.

Insertion Procedure

When the lesion was severe, predilatation was performed with a 2.0-mm balloon using standard percutaneous coronary angioplasty techniques. All stents were manually mounted on a balloon that matched the angiographic reference lumen diameter. The stent was then overdilated with a balloon approximately 0.5 mm larger than the reference lumen diameter. To avoid balloon inflation outside of the stented segment of the vessel, a 9-mm-long balloon (Short Speedy, Schneider Europe) was used for final dilatation. The final dilatation was performed at higher pressures, if necessary.

The procedure end point was achieved when the operator determined that maximal stent expansion had occurred based on the angiographic evidence of a step up into the stented area and a step down into the distal unstented segment. Ordinarily, the procedure would be terminated at this point, but for the purpose of this study, IVUS imaging was then performed using a 3.9-F monorail system with a 25-MHz ultrasound transducer (Interpret Catheter, InterTherapy/CVIS). The imaging catheter was positioned under fluoroscopic guidance distal to the stent, and images were recorded continuously as the catheter was withdrawn manually through the stented segment. After the stented area was interrogated with a single pullback, the catheter was repositioned to identify the tightest segments within the stented portion. If the operator and ultrasound reviewer believed that there was a possibility to improve stent expansion, further balloon dilatations were performed using a larger balloon or higher pressure. The initial concept was to obtain a lumen cross-sectional area (CSA) approximately 70% of the expected CSA of the chosen balloon. IVUS imaging and balloon dilatation were repeated until a satisfactory lumen area and uniform expansion were achieved or no further improvement could be obtained.

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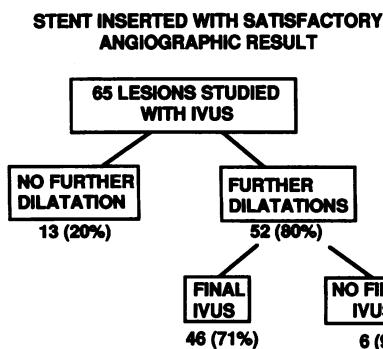


Fig 1. Flow chart of the 65 lesions visualized with intravascular ultrasound (IVUS) after stent insertion. All patients had a satisfactory angiographic lumen diameter result before the first ultrasound examination.

In 13 lesions (20%), no further balloon dilatation was performed after the first IVUS. The other 52 lesions (80%) underwent further balloon dilatation (Fig 1). The average number of times that the stent had to be crossed with the ultrasound catheter and redilated to obtain an adequate final result was 2.4 ± 0.6 (range, 2 to 4). To simplify the presentation of these results, the measurements reported after the first observation by IVUS are defined as the first step, and the final step is defined as the ultrasound and angiographic results after the last balloon dilatation.

Quantitative Measurements

Intravascular Ultrasound

After an ultrasound examination was completed, the videotape was reviewed, and the narrowest area within the stent was identified. The image was digitized to perform the quantitative analysis with graphics software incorporated in the ultrasound console. The major and minor diameters of the lumen and vessel were measured (Fig 2A). The lumen CSA was planimetered at the interface with the stented plaque. The vessel CSA is defined by IVUS as the area bounded by the interface of the echodense plaque and the echolucent media. The lumen minor diameter divided by the major diameter was calculated as the symmetry index. The lumen CSA divided by the vessel CSA was calculated as the percent lumen area. Ultrasound images were identified for reference sites several millimeters proximal and distal to the stented area (Fig 2B). After a stent is inserted, the intense echo reflections from the metallic struts frequently prevent adequate ultrasound penetration to visualize the plaque-media boundary. Therefore, for the purpose of calculating percent lumen area, the vessel CSA within the stented section was assumed to be the average of the vessel

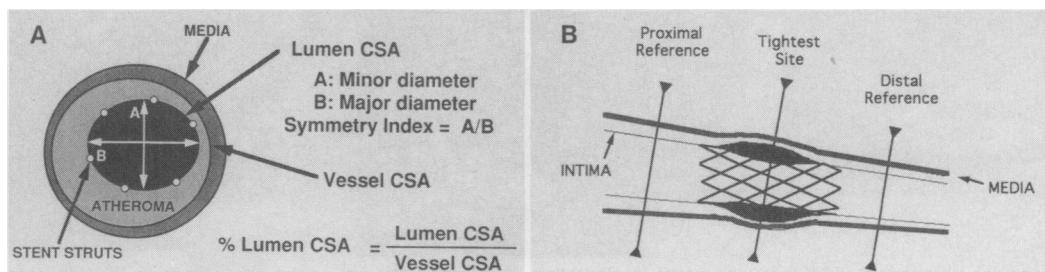


Fig 2. Schematics: Intravascular ultrasound (IVUS) measurements. A, Perimeter of the lumen and border between the atheroma and media where measurements were taken. Symmetry index is defined as the minor diameter (A) divided by the major diameter (B). Vessel cross-sectional area (CSA) is defined as the area that the vessel would be if there were no atheroma and is measured at the perimeter between the inner aspect of the media and the edge of the atherosclerotic plaque. The percent lumen CSA is then defined as the lumen CSA divided by the vessel CSA. B, Position along the length of the artery where measurements were obtained from the IVUS examination. The tightest segment along the length of the stented portion of artery was compared with proximal and distal reference sites. The boundary of the media and atheroma was measured at the reference sites to calculate the average vessel CSA. The lumen within the stented segment was compared with this average vessel CSA.

CSA measured within 5 mm proximal and distal to the stented segment.

Quantitative Angiographic Measurements

The minimum lumen diameter of the stenosis and the reference lumen diameter were measured before any intervention, after the initial stent insertion (first step), and after the final series of balloon dilatation guided by IVUS (final step). The angiographic percent diameter stenosis was calculated by selecting the angiographically normal proximal segment as the reference point. The lesion length was also measured. In one laboratory, 48 lesions were measured using a micrometer from the projected angiographic film image. In the second laboratory, 17 lesions were measured using the Philips automated DCI digital computer system. In both methods, the diameter of the guiding catheter was used as the calibration reference. Measurements were made from end-diastolic frames or the frame that best demonstrated the stenotic site.

Statistics

Data are expressed as mean \pm SD. Comparisons between groups were analyzed by the paired Student's *t* test and ANOVA when multiple groups were compared. Differences between groups were considered to be statistically significant at $P < .05$.

Results

Intracoronary stents were successfully placed in 64 lesions in 62 patients. Table 1 shows the patient profile, the vessels treated, and the number and type of stent inserted. Fig 3 shows an example of stent underexpansion diagnosed by IVUS. The lesion was treated with two short stents and dilated with a 3.5-mm balloon at 12 atm. The angiogram showed a good result, but IVUS revealed a relatively small lumen CSA of 6.4 mm². This area corresponds to 66% of the CSA of a 3.5-mm balloon. After further inflation with a 4.5-mm balloon at 10 atm, the lumen CSA improved to 9.9 mm². Fig 4 shows that a stent may be asymmetrically expanded despite a good angiographic result. After further inflation, the lumen symmetry improved. Fig 5 demonstrates incomplete apposition of the stent struts to the intimal surface. After further inflation, all struts were appropriately secured to the intimal surface.

Angiographic Measurements

Table 2 shows the angiographic results, the average balloon size, and the maximum inflation pressures of the 52 lesions that received further dilatations after the first

TABLE 1. Patient and Procedure Characteristics

Age, y	58.6±9.6	
Men	55 (87%)	
Treated vessel		
LAD	40 (62%)	
LCx	10 (15%)	
RCA	14 (22%)	
LMT	1 (1%)	
Lesion length	13±10 mm	
Single stent	18 (28%)	
Multiple stents	47 (72%)	
Stent Type	No. of Lesions (%)*	Average No. of Stents per Lesion
Standard stent	12 (18%)	1.7
Short stent	48 (74%)	2.4
Biliary stent	10 (15%)	1.0
Renal stent	1 (2%)	1.0

LAD indicates left anterior descending coronary artery; LCx, left circumflex artery; RCA, right coronary artery; LMT, left main trunk; standard stent, Palmaz-Schatz coronary stent; and short stent, Palmaz-Schatz coronary stent cut at articulation site.

*Six lesions were treated with more than one type of stent.

step. The average lumen diameter before angioplasty was 0.96 ± 0.49 mm. The lesion diameter after the first step (an angiographically satisfactory result) was 3.12 ± 0.47 mm ($P<.0001$). The lesion diameter after the final balloon dilatation after repeated IVUS assessment was 3.61 ± 0.49 mm ($P<.0001$). The angiographic percent diameter stenosis at baseline was $72\pm 15\%$. After the initial set of inflations, the angiographic diameter stenosis was $9\pm 13\%$, and after the final step with further dilatations, the angiographic percent stenosis was $-4\pm 12\%$ (that is, the lumen at the tightest segment was larger than the reference lumen; $P<.0001$). The average balloon size used for the initial set of dilatations was 3.7 ± 0.3 mm (3.0 to 4.5 mm). The average balloon size used in the final-step dilatations was significantly larger, at 4.1 ± 0.4 mm (3.5 to 5.0 mm, $P<.0001$). The average maximum inflation pressure was 11.1 ± 1.9 atm (8 to 16) during the first-step dilatations and was 12.0 ± 2.6 atm (7 to 17) at the final step ($P=NS$).

Ultrasound Measurements

The relation between the expected balloon CSA (if full expansion were achieved at the pressure used) and the actual lumen CSA obtained at the tightest point of the stented segment is shown in Table 3. After the first step, 65 lesions were evaluated by IVUS. Using 3.0- to 4.5-mm balloons, the average lumen CSA obtained as a percent of the expected balloon size of CSA varied between 50% and 75%. After the final step, 46 lesions

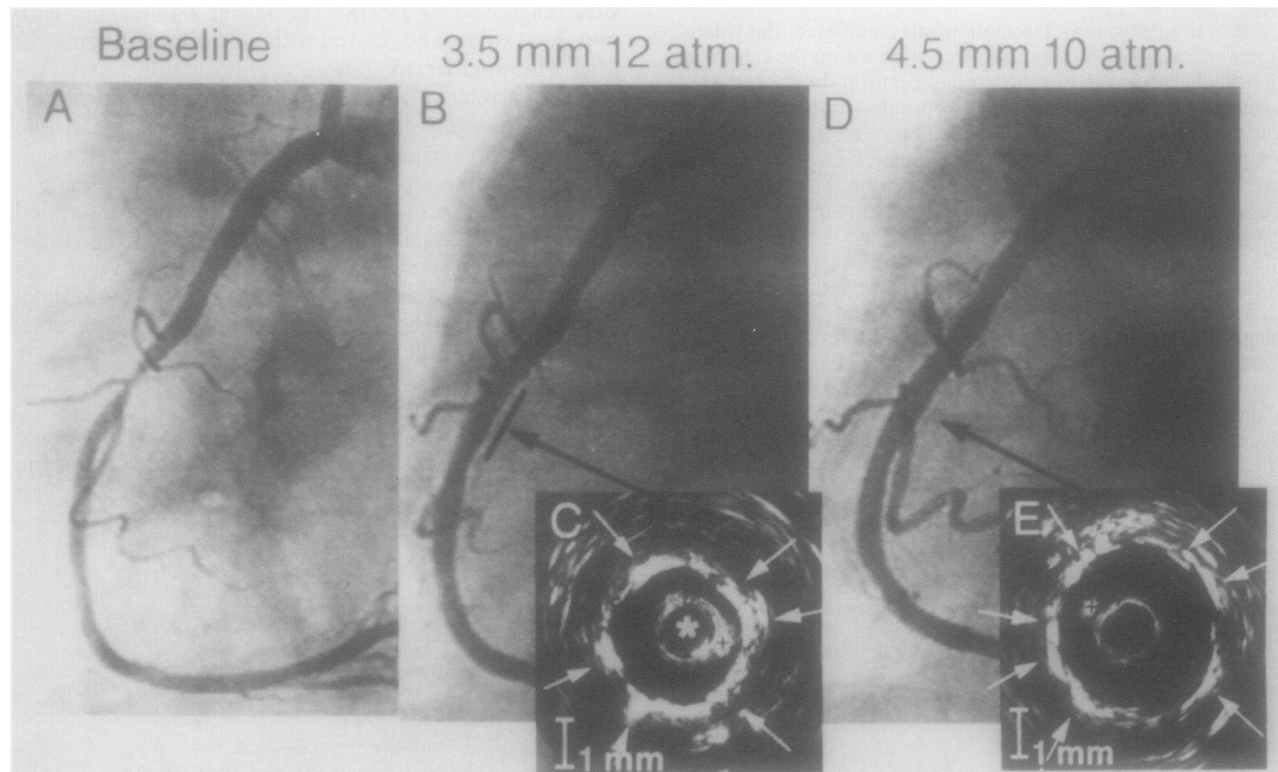


Fig 3. Intravascular ultrasound (IVUS) guided stent implantation. A, Right coronary artery angiogram in the left anterior oblique projection demonstrates a stenosis in the middle segment. B, After insertion of two overlapping short stents with a 3.5-mm-diameter balloon inflated at 12 atm, the angiogram shows no evidence of residual stenosis. Black line indicates length of the stented segment. C, IVUS image after stent insertion demonstrates adequate stent apposition with the wall, a minor diameter of 2.6 mm, and a cross-sectional area of 6.6 mm². Central black circle corresponds to the position of the ultrasound catheter (*); guide wire runs parallel to the catheter in this monorail design (+). Individual metallic struts of the stent are indicated by white arrows. D, Based on ultrasound images, the stented segment was finally redilated with a 4.5-mm balloon at 10 atm. The angiogram shows a step up of lumen diameter into the stented area. E, Corresponding ultrasound image after inflation with a 4.5-mm balloon demonstrates that the lumen has enlarged 62%, to 10.7 mm². Stented lumen-to-vessel cross-sectional area ratio improved from 40% to 65%.

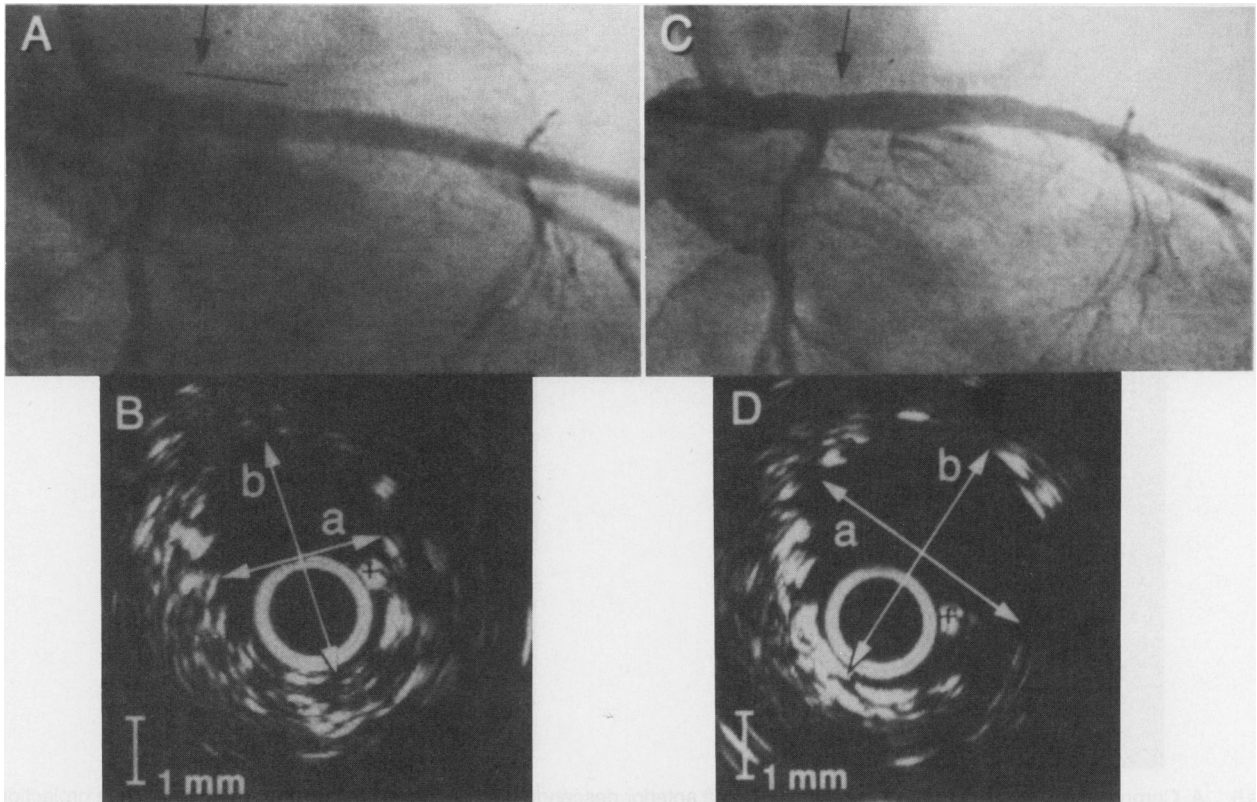


Fig 4. Angiograms. A, The proximal left anterior descending coronary artery demonstrates a satisfactory angiographic result after insertion of a 10-mm Palmaz biliary stent with a 4.0-mm balloon inflated at 10 atm. B, The intravascular ultrasound image corresponding to the level of the arrow in A reveals an asymmetrically inflated lumen with major and minor diameters of 3.7 and 2.7 mm, respectively. The symmetry index is 0.65. C, The artery was dilated with the same 4.0-mm balloon but at a higher pressure of 15 atm. The angiogram shows a satisfactory result without significant change from A. D, Ultrasound image at the same level of the artery after the last inflation. Major and minor diameters have increased to 4.1 and 3.6 mm. In addition, the lumen is more symmetrically expanded, with a symmetry index of 0.88.

were evaluated by IVUS. Using 3.5- to 5.0-mm balloons, the average lumen CSA in the tightest point of the stented segment varied between 61% and 71% of the expected balloon CSA.

Forty-six lesions were studied at the first step and final step by IVUS. The measurements derived from the IVUS images are presented in Table 4. The mean tightest lumen CSA in the stented segment was 6.9 ± 2.0 mm² after the initial set of balloon dilatations and increased to 9.0 ± 2.4 mm² after the final step ($P < .0001$). After the first step, the minimum lumen diameter within the stented segment was 2.7 ± 0.4 mm, which increased to 3.1 ± 0.5 mm after the final set of dilatations ($P < .0001$). The major lumen diameter increased from 3.2 ± 0.8 to 3.6 ± 0.5 ($P < .0001$). The symmetry index was 0.83 ± 0.10 after the first step and was not significantly different (0.86 ± 0.09) after the final step.

Eighty percent of lesions received further dilatation based on the observations of IVUS. One manifestation of underexpansion is that the mean lumen CSA after the first step was smaller than the distal reference lumen CSA. Fig 6 demonstrates the presence of underexpansion by plotting the percentile distribution of the stented segments CSA compared with the proximal and distal reference sites. The stented lumen areas are below the curves for the proximal or distal reference CSA in the majority of cases after the initial set of dilatations. The stented lumen CSA only falls between the measurements of the proximal and distal segments

after the IVUS-guided final set of balloon dilatations. It was possible to improve this underexpansion in all cases with repeat balloon dilatation using larger balloons or higher pressures. The percent lumen CSA at the stented segment increased from $49 \pm 10\%$ to $65 \pm 10\%$ between the first step and the final step ($P < .0001$).

The effect on the lumen symmetry of further balloon inflations is demonstrated in Fig 7. Although there was no statistical difference between the mean symmetry index after the first step (.83) compared with after the final step (.86), there was a trend of improved symmetry index after further inflations. The unstented reference vessel symmetry index also varied between 0.69 and 1.0.

A comparison between the balloon size used and the vessel diameter (media to media) assessed by IVUS is demonstrated in Fig 8. In this figure, a histogram of the percent of lesions is plotted against the ratio of the balloon diameter divided by the average minor vessel diameter after the first step of initial balloon inflations (Fig 8A) and after the final-step series of inflations (Fig 8B). After the first step, the mean balloon-vessel ratio was 0.97 ± 0.10 (range, 0.71 to 1.27). After the final step, the mean balloon-vessel ratio at the proximal site was 1.06 ± 0.11 (range, 0.89 to 1.45). In the one case in which a vessel rupture occurred, the balloon-vessel ratio was 1.44.

Complications

A major complication occurred in one patient who suffered a rupture of the native coronary artery that was

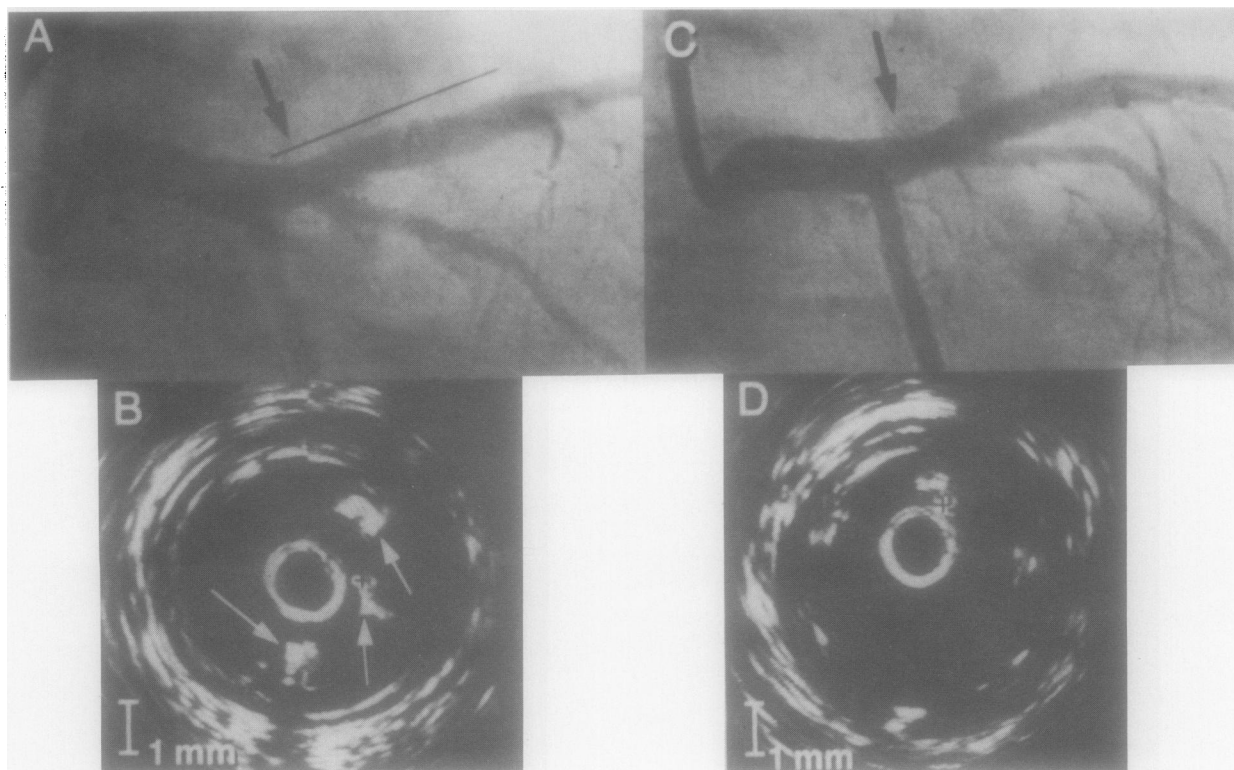


FIG 5. A, Coronary angiogram of the left main artery and left anterior descending coronary artery in the right anterior oblique projection after insertion of four half-stents in the proximal segment of the left anterior descending coronary artery. Black line indicates length of artery where the stents were implanted. A 4.5-mm balloon was used and inflated to 10 atm. B, Despite the use of this large balloon, intravascular ultrasound imaging reveals that the proximal section of the stent struts (arrows) are not apposed to the intimal surface. The guide wire (+) could be distinguished from the struts during real-time imaging by its motion relative to the catheter and stent struts. C, After inflation with a 5-mm balloon at 10 atm, the angiogram shows a satisfactory result without significant change from the previous angiogram. D, Corresponding intravascular ultrasound image now demonstrates that all stent struts were fully expanded and attached to the intimal surface.

stented distal to the anastomosis of a vein graft. The initial ultrasound image demonstrated the stent under expansion in the presence of a dense, fibrotic plaque. Despite optimal balloon size and high pressure, the stent did not expand adequately. Rupture of the coronary artery occurred when a balloon that was 1.5 mm larger than the ultrasound-measured distal reference vessel was inflated to 15 atm. The patient underwent emergency coronary artery bypass surgery but suffered a large anterior wall myocardial infarction and died 2 days after emergency bypass surgery. There were no other cases of acute myocardial infarction or subacute thrombosis within the hospital stay. After discharge, all patients were followed clinically. At follow-up 1 month after the procedure, there was no incidence of subacute

thrombosis, myocardial infarction, repeat percutaneous transluminal coronary angioplasty, or coronary bypass surgery. One patient died from renal failure. Inflation with a larger balloon created a small dissection in two patients that required placement of additional short stents. Both patients had a successful outcome. There were no complications associated with ultrasound imaging.

Discussion

Despite impressive results with stent implantation for elective or emergency indications, there is still a significant risk of thrombotic complications of 0.6% to 3% after elective Palmaz-Schatz stent insertion.^{1-3,10,11} The incidence is even higher (6% to 23%)¹⁰⁻¹⁵ for emergent

TABLE 2. Angiographic Measurements, Balloon Size, and Maximum Balloon Pressure

	Baseline	First Step	Final Step
Minimum lumen diameter, mm	0.96±0.49	3.12±0.47	3.61±0.49*
Proximal reference diameter, mm	3.40±0.41	3.44±0.41	3.48±0.39
% Diameter stenosis	72±15	9±13	-4±12*
Balloon size, mm		3.7±0.3	4.1±0.4*
Maximum inflation pressure, atm		11.1±1.9	12.0±2.6

First step is after a satisfactory angiographic result; final step is after final dilatation using the maximum-size balloon guided by intravascular ultrasound measurement.

* $P < .0001$, first step vs final step. $n = 52$.

TABLE 3. Relation Between Balloon Size and Achieved Lumen Cross-sectional Area

Balloon Size, mm	Expected Balloon CSA, mm ^{2*}	Achieved Lumen CSA, mm ²	Lumen Area as % of Expected Balloon CSA
After first step			
3.0 (n=5)	7.1	5.3±1.4	75%
3.5 (n=29)	9.6	6.2±1.4	65%
4.0 (n=29)	12.6	7.7±1.8	61%
4.5 (n=2)	15.9	7.9±0.6	50%
After final step			
3.5 (n=7)	9.6	5.9±0.8	61%
4.0 (n=26)	12.6	9.0±1.5	71%
4.5 (n=9)	15.9	9.4±1.6	59%
5.0 (n=4)	19.6	13.4±2.9	68%

CSA indicates cross-sectional area.

*Expected at nominal pressure.

implantation. It is not clear whether the risk of thrombosis and restenosis is due to the stimulation of the metallic foreign body or hemodynamic factors. If the metal predisposes to thrombosis, the highest risk should be early, since animal studies demonstrate that metal stents are covered by a thin intima after 1 week.^{23,24}

It is generally accepted that proper stent placement without inflow or outflow obstruction is important to limit acute complications, subacute stent thrombosis, and possible restenosis. Restenosis after stent insertion is reported as 16% for de novo lesions and 36% for restenotic lesions.⁴ There is some preliminary evidence to suggest that a larger acute gain in minimum lumen diameter may diminish the restenosis rate at 6 months.⁸ It is also assumed that restenosis is only due to proliferation of cellular matrix and new tissue growth through the slots of the stent. The results of the present study question the adequacy of using angiography to assess the success of stent deployment. Despite adequate angiographic results with a step up into the stented area and a step down into the distal segment of the artery, IVUS imaging demonstrated a high frequency of incom-

pletely expanded stents. These results suggest that some of the complications of subacute thrombosis or restenosis may be due to inadequate stent expansion during initial deployment.

The initial attempt in this study was to successfully deploy the stents using standard angiographic criteria. This was achieved; the angiographic minimum lumen diameter was 3.13 mm and the percent stenosis was 9±13% after initial deployment of the stent. These values are similar to those obtained in recent reports. Gordon et al⁵ reported a minimum lumen diameter of 3.0±0.7 mm and a percent diameter stenosis of 16±10%. Haude et al⁹ obtained a minimum lumen diameter of 3.0±0.3 mm and a residual stenosis of 9±11%. Kimura et al¹⁰ had a minimum lumen diameter of 2.9±0.4 mm and a diameter stenosis of 15%. However, based on the ultrasound assessment in the current study, further dilatations were performed that produced a final minimum lumen diameter of 3.61±0.49 mm, with a final percent diameter stenosis of -4±13%. The average improvement in minimum lumen diameter of 0.5 mm is statistically significant ($P<.0001$) and repre-

TABLE 4. Intravascular Ultrasound Measurements

	Proximal Reference	Stented Lesion		Distal Reference
		First Step	Final Step	
Lumen				
CSA, mm ²	10.5±3.3	6.9±2.0	9.0±2.4*	7.9±3.3
Minor diameter, mm	3.3±0.6	2.7±0.4	3.1±0.5*	2.9±0.6
Major diameter, mm	3.7±0.6	3.2±0.8	3.6±0.5*	3.2±0.8
Minor/major diameter	0.89±0.08	0.83±0.10	0.86±0.09	0.90±0.07
Vessel				
CSA, mm ²	15.6±3.9			12.4±3.7
Minor diameter, mm	4.2±4.5			3.7±0.6
Major diameter, mm	4.5±0.6			4.0±0.6
Lumen CSA/vessel CSA, %	67±22	49±10†	65±10†	64±15

CSA indicates cross-sectional area.

* $P<.0001$, between the first step and the final step. n=46.

†The vessel CSA at the stented lesion was calculated as (proximal plus distal reference vessel CSA) divided by 2.

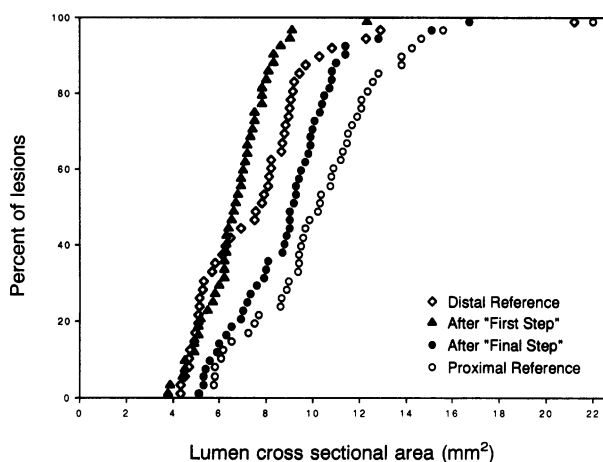


Fig 6. Plot of percentile distribution of lumen cross-sectional areas (CSA). Lumen CSA is plotted on the horizontal axis for the proximal and distal reference sites as well as for the narrowest cross section within the stent after the initial satisfactory angiographic result (first step) and after the final series of balloon inflations (final step). Despite an adequate angiographic result after the first series of inflations (\blacktriangle), the majority of lesions showed a lumen CSA within the stent that was less than the proximal or distal reference areas. After inflation with a larger balloon or higher pressures (\bullet), the lumen CSA improved and was within the range of values between the proximal and distal reference dimensions.

sents a 16% increase in angiographic minimum lumen diameter and a 34% increase in minimum lumen CSA.

During these initial observations with IVUS imaging of stent insertion, we evaluated several criteria to use as guidelines for directing balloon dilatation of the stent. The underlying assumption of establishing appropriate criteria is that maximizing the stented lumen CSA would more likely yield a lower restenosis rate and incidence of subacute thrombosis. However, the aggressive use of larger balloons or higher pressures to maximize the stented lumen CSA must be tempered with the potential for arterial rupture.

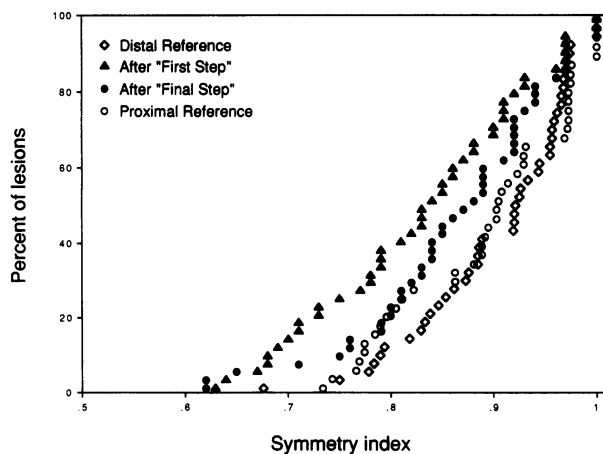


Fig 7. Symmetry index is plotted on the horizontal axis for the proximal and distal reference sites of the vessel as well as for the tightest cross section within the stented segment after the first step of balloon inflations and after the final step. Vertical axis represents the cumulative percent of lesions studied. Although there was no statistically significant difference between the mean values for the symmetry index between the first step and the final step, there is a trend to increased symmetry after the final series of balloon inflations.

In this initial experience with IVUS guidance of stent insertions, several guidelines were tried but eventually discarded. The first guideline that was used was to obtain a lumen CSA 70% the size of the balloon chosen to inflate the stent. The balloon size was selected to be 0.5 mm greater than the angiographic reference lumen size. However, despite apparent maximum inflation at usual or elevated pressures, the achieved lumen CSA was only 50% to 75% of the expected lumen area (Table 3). Based on these observations, it was decided to use larger balloons or higher pressures to achieve the expected lumen CSA within the stented segment. The second guideline that was developed was to use a balloon diameter equal to the IVUS reference vessel diameter. The reference vessel diameter cannot be assessed by measuring the lumen diameter on angiography but is only obtained by the ultrasound measurement of the media-to-media diameter. However, further analysis of our data revealed that a balloon size equal to the reference vessel diameter, although large enough for small vessels, is insufficient to maximize the lumen CSA in larger vessels (Fig 6). The third guideline that was evaluated was the use of an absolute value for lumen CSA. As demonstrated in Fig 6, in half of the cases, a lumen CSA >9 mm² was achieved. Although this may be optimal for larger proximal vessels, it may not be appropriate for large vein grafts or when there is a smaller distal vessel. A more appropriate criteria would consider the relative size of the reference vessel (both proximally and distally) to prevent rupture of the vessel and still permit aggressive use of larger balloons.

From an analysis of the data in Fig 8, the one vessel rupture occurred in which the balloon size divided by the average minor vessel diameter was 1.44. To minimize the risk of vessel rupture, we recommend that a balloon is chosen with a balloon-to-vessel ratio <1.0 times the average of the proximal and distal vessel minor diameters. The vessel diameter is determined at the time of the study with IVUS measurement of the narrowest media-to-media dimension. For arteries with diffuse disease or distal vessel tapering, we recommend use of a short balloon that is inflated completely within the stented segment, especially when inflation pressure exceeds 15 atm. The object of using this balloon-to-vessel ratio criterion is to obtain a stented lumen CSA $\geq 60\%$ of the average reference vessel (media to media) CSA. The true vessel area within the stented segment cannot be adequately measured directly by IVUS because the intense echo reflections from the metallic struts prohibit adequate visualization of the media. Even at the angiographically normal proximal and distal reference sites, there is a moderate amount of atherosclerosis present that represents approximately 35% of the available vessel CSA bounded by the media.²⁵ This corresponds to a measured percent lumen CSA of 67% for the proximal reference area and 64% for the distal reference area. The stented segment lumen-vessel CSA improved from 49% to 65% after the ultrasound-guided series of balloon dilatations. These observations are consistent with previous histological and in vivo ultrasound measurements. Stiel et al²⁶ reported the angiographic normal reference lumen CSA was 70% of the histologically measured vessel CSA in human coronary arteries.

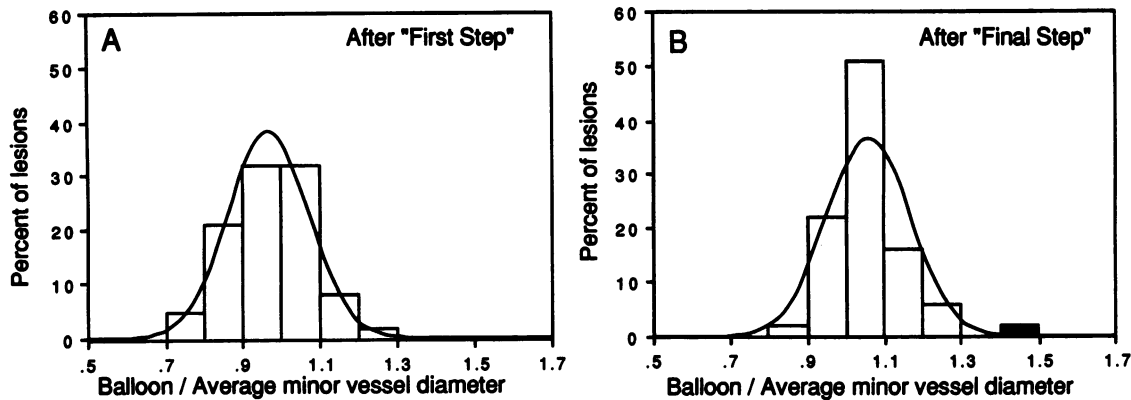


Fig 8. Histograms of balloon-to-vessel diameter ratio demonstrate the percent of lesions on the vertical axis compared with the ratio of the balloon diameter to the average minor vessel diameter plotted on the horizontal axis. A, Measurements after the first step of balloon inflations. B, Measurements after the final step of balloon inflations. Black bar corresponds to the patient who developed rupture of the left anterior descending coronary artery when the diameter of the vessel by intravascular ultrasound was not used to limit the size of the balloon.

Symmetry Index

Although the mean lumen CSA increased 30% between the first and final series of balloon inflations, the symmetry index of the stented lumen did not change significantly (0.83 to 0.86). There were six (9%) lesions that had a symmetry index <0.7 after the first step. The symmetry index of five of these lesions improved to >0.7 after the final set of inflations. There were three lesions in which the symmetry index decreased to <0.7 after the final step despite the fact that the lumen CSA was enlarged. In these instances, it appears that the less-diseased perimeter of the vessel was expanded, but the portion of the vessel associated with dense fibrocalcific disease did not respond to larger balloons or higher inflation pressures. Attempts to improve the symmetry index with further expansion are not recommended when the initial inflations are unsuccessful or result in a decrease in the symmetry index.

Adequate apposition of the metallic stent to the wall of the artery cannot be assessed by angiography. In four lesions (6%), IVUS showed incomplete stent expansion, with portions of the metallic struts not touching the wall of the artery after the first step. Two of these cases occurred at the ostium of the LAD, one in the mid LAD and one in an ectatic RCA.

Angiographic Versus Ultrasound Assessment

The IVUS images provided information that was unique compared with angiography. Angiography and ultrasound imaging are very different forms of analysis. Although angiography provides a rapid means of assessing the diameter of the lumen along the length of the vessel, IVUS provides a circumferential assessment of CSA that is not obscured by overlapping vessels or variations in projection. This is especially pertinent to the study of stent implantation in which there may be a very focal or short stenosis (so-called napkin ring stenosis). Angiography may fail to detect these narrowed segments within the stent because they may be <1 mm in length. Unless the column of contrast is exactly perpendicular to the x-ray beam, this narrowing may be missed on angiography. The ultrasound catheter images the artery from within the lumen and therefore is more likely to detect the area of tightest narrowing, even

though it may be very focal. Since the resistance to flow is inversely proportional to the square of the CSA,²⁷ even a short narrowing in a stented segment will decrease flow and create conditions for thrombosis. In addition, the magnification scale is greater with ultrasound images that may facilitate the recognition of underexpansion compared with angiography. Quantitative angiographic analysis in fact did demonstrate a 13% point change in lumen stenosis (from 9% to $-4%$) between the first step and final step, but it is difficult to appreciate this visually on the angiographic replay during the procedure.

These data suggest that IVUS imaging is useful during deployment of intracoronary stents for three reasons: (1) it helps appreciate underexpansion of the stent, (2) it demonstrates incomplete apposition of the struts with the luminal surface, and (3) it provides quantitative data that can be used to choose an appropriately sized balloon to maximize stent lumen area and yet maintain safety.

The present study describes our preliminary results to support these recommendations of ultrasound criteria to guide stent implantation. This was not designed as an outcome study to test whether the criteria predict the clinical results after stent insertion. A larger-scale outcome study is currently being performed to test the hypothesis that if these proposed criteria are met, then the need for anticoagulation after the procedure may be obviated.

Study Limitations

Using IVUS to make these measurements and repeat balloon inflations if necessary increases the length of the procedure. This may increase the risk to the patient, especially since larger balloons or higher pressures are recommended. However, there was only one serious complication in this series, and that was in a situation in which the findings by IVUS were not heeded to limit the size of the balloon.

This study was not a randomized clinical trial to assess outcome, and it cannot be used to determine whether the approach and criteria we recommend will be beneficial in decreasing the long-term subacute thrombosis and restenosis rates.

Conclusions

IVUS evaluation after stent insertion demonstrates a significant degree of underexpansion compared with the estimation by coronary angiography. Using ultrasound imaging, 80% of our cases underwent further balloon dilatation despite the initial appearance of an optimal angiographic result. This preliminary experience demonstrates that IVUS assessment is an important adjunct to assist proper stent placement. The results of this study give credence to the hypothesis that this technique is superior to angiographic guidance alone for stent insertion. Further studies are necessary to evaluate the effectiveness of this approach on the restenosis rate or to determine whether the subacute thrombosis rate can be diminished by using a less aggressive anticoagulation protocol than is currently being used.

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